

FDA will designate it as an original submission. Revisions that require a consult to another division will be considered to introduce “significant new concepts or creative themes.”

APPENDIX B-1
EXAMPLE 1: ORIGINAL SUBMISSIONS
If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200

submissions in fiscal year 2009; 224 submissions in fiscal year 2010; 200 submissions in fiscal year 2011; and 250 submissions in fiscal year 2012, the review metrics will be as follows:

	FY 08: 150 submissions	FY 09: 200 submissions	FY 10: 224 submissions	FY 11: 200 submissions	FY 12: 250 submissions
Cohort 1 (150 submissions)	75 (50% of 150)	90 (60% of 150)	105 (70% of 150)	120 (80% of 150)	135 (90% of 150)
Cohort 2 (50 submissions)		25 (50% of 50)	30 (60% of 50)	35 (70% of 50)	40 (80% of 50)
Cohort 3 (24 submissions)			12 (50% of 24)	0 (60% of 0)	17 (70% of 24)
Cohort 4 (0 submissions)				0 (50% of 0)	0 (70% of 0)
Cohort 5 (26 submissions)					13 (50% of 26)
Total Target for 45 Day Review Metric	75	115	147	155	205

EXAMPLE 2: ORIGINAL SUBMISSIONS
If participants indicate the intent to submit 150 submissions in fiscal year 2008; 200

submissions in fiscal year 2009; 250 submissions in fiscal year 2010; 300 submissions in fiscal year 2011; and 350 submissions in fiscal

year 2012, the review metrics will be as follows:

	FY 08: 150 submissions	FY 09: 200 submissions	FY 10: 250 submissions	FY 11: 300 submissions	FY 12: 350 submissions
Cohort 1 (150 submissions)	75 (50% of 150)	90 (60% of 150)	105 (70% of 150)	120 (80% of 150)	135 (90% of 150)
Cohort 2 (50 submissions)		25 (50% of 50)	30 (60% of 50)	35 (70% of 50)	40 (80% of 50)
Cohort 3 (24 submissions)			25 (50% of 50)	30 (60% of 50)	35 (70% of 50)
Cohort 4 (50 submissions)				25 (50% of 50)	30 (60% of 50)
Cohort 5 (50 submissions)					25 (50% of 50)
Total Target for 45 Day Review Metric	75	115	160	210	265

EXAMPLE 3: RESUBMISSIONS
If participants submit 75 resubmissions in fiscal year 2008; 99 resubmissions in fiscal

year 2009; 123 resubmissions in fiscal year 2010; 147 resubmissions in fiscal year 2011;

and 171 resubmissions in fiscal year 2012, the review metrics will be as follows:

	FY 08: 75 resubmissions	FY 09: 99 resubmissions	FY 10: 123 resubmissions	FY 11: 147 resubmissions	FY 12: 171 resubmissions
Cohort 1 (75 submissions)	37 (50% of 75)	45 (60% of 75)	52 (70% of 75)	60 (80% of 75)	68 (90% of 75)
Cohort 2 (24 submissions)		12 (50% of 24)	14 (60% of 24)	17 (70% of 24)	19 (80% of 24)
Cohort 3 (24 submissions)			12 (50% of 24)	14 (60% of 24)	17 (70% of 24)
Cohort 4 (24 submissions)				12 (50% of 24)	14 (60% of 24)
Cohort 5 (24 submissions)					12 (50% of 24)
Total Target for 30 Day Review Metric	37	57	78	103	130

IRAQ STUDY GROUP

Mr. SALAZAR. Mr. President, last night, we passed the Department of Defense Authorization bill. I want to comment briefly on the debate we had during consideration of that legislation related to the war in Iraq. I am frustrated that we did not reach a bipartisan consensus on a new way forward that could begin to bring an end to this conflict.

When I introduced the Iraq Study Group Recommendations Implementation Act last spring with Senator ALEXANDER and a bipartisan group of our colleagues, I was hopeful we could work constructively with the President toward the goal of having our troops redeployed by the spring of 2008. I was hopeful that we would send a strong signal—with a bipartisan group that eventually grew to 17 Senators—that we should get out of the combat business in Iraq as quickly as possible.

The Iraq Study Group Report was issued 10 months ago. Its core recommendation was that we transition our military mission from combat to training, supporting, and equipping Iraqi security forces. The report said that we should condition our support of the Iraqi Government on its performance in meeting important milestones. The report contemplated that we could be out of the combat business by March 31, 2008.

The report was anticipated with great fanfare. But when it came out, the Bush administration failed to embrace it. The Iraqi Government has failed to meet most of the benchmarks described in the report. General Petraeus has testified, essentially, that

we should maintain our combat mission for the foreseeable future. And that March 31 date is only 6 months away.

I still believe in the report. It is still relevant, and it is still important. It sets forth a comprehensive military, political, and economic strategy for bringing a responsible end to the war in Iraq.

But I believe we must build upon the report and take decisive action now to redefine our mission in Iraq and set a clear course for the redeployment of our troops.

Ten months after the Iraq Study Group issued its report, we have failed to begin the transition of our mission that was central to their recommendations. That transition in mission is the key to encouraging the Iraqi Government to take responsibility for the future of their country. The Government Accountability Office has concluded that the Iraqi Government has failed to take that responsibility by meeting the reasonable benchmarks set forth by the Iraq Study Group.

I continue to believe that we must follow the core principles laid out in the Iraq Study Group Report. I continue to believe we need a bipartisan solution to bring this conflict to a responsible end. And I thank each of the cosponsors of our amendment, Republicans and Democrats, for their willingness to join in this important effort. They include Senators ALEXANDER, BENNETT, COLEMAN, COLLINS, DOMENICI, GREGG, SPECTER, and SUNUNU from the Republican side and Democratic Senators PRYOR, CASEY, CARPER, CONRAD,

LANDRIEU, LINCOLN, MCCASKILL, and BILL NELSON.

I believe now is the time to build upon the principles set forth by the Iraq Study Group. We must begin a transition of mission from combat to training and support. We must demand more from the Iraqi Government and send a strong and unequivocal message that our commitment is not open-ended. I believe these actions are consistent with the recommendations of the Iraq Study Group, and I remain hopeful that our legislation can be the basis for a constructive, bipartisan solution to the war in Iraq.

HONORING OUR ARMED FORCES

SECOND CLASS CHARLES LUKE MILAM

Mr. SALAZAR. Mr. President, I wish to reflect on the life and service of Navy Hospital Corpsman Second Class Charles Luke Milam. Luke was killed last Wednesday in a rocket attack near the town of Musa Qula, Afghanistan. He was 26 years old.

Luke Milam was a giant of his generation, a man who served his country and those around him with dignity, courage, and honor. I cannot begin to paint the picture of someone so deeply respected by those with whom he served, so committed to helping others.

Luke Milam grew up in Littleton, CO, the youngest of four siblings. He was smart, friendly, and athletic. He loved the mountains of Colorado and spent his time biking, backpacking, hiking, and canoeing.